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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,718	01/09/2007	**Carl T Brighton**	UPN-4914	4352

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,718	BRIGHTON, CARL T	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-13 and 16-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-10, 13 and 18 of U.S. Patent No. 7,465,566, as follows: instant claims 7-13, 22 and 23 over patented claim 18; instant claims 16 and 19 over patented claim 4; and instant claims 17, 18, 20, 21 and 24-26 over patented claims 5-10 and 13, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

> [t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

The instant claim in each instance is more narrowly drawn than the patented claim. However, the portion of US Patent 7,465,566 that supports each of the instant claims teaches each of the narrower limitations of the instant claims.

Claims 1-13 and 16-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-11, 13 and 16-24 of U.S. Patent No. 7,374,916, as follows: instant claims 10-12 over patented claim 11; instant claims 16 and 26 over patented claim 16; instant claims 22 and 23 over patented claim 22; and instant claims 1-9, 13, 17-21, 24 and 25 over patented claims 1, 2, 4-10, 13, 16-21, 23 and 24, respectively Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference

claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). The MPEP states, at §804, that

> [t]he specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

The instant claim in each instance is more narrowly drawn than the patented claim. However, the portion of US Patent 7,374,916 that supports each of the instant claims teaches each of the narrower limitations of the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brighton et al. (reference 67 on the IDS filed 13 February 2007).

Claim 1 is drawn to a method of specifically and selectively up-regulating the gene expression of bone morphogenetic protein(s) in targeted tissue, comprising the steps of generating at least one specific and selective signal having a frequency from 30 kHz to 120 kHz that when applied to a field generating device operatively disposed with respect to said targeted tissue causes the generation of a field having an amplitude of about 2 to 40 mV/cm in the targeted tissue that is specific and selective for the up-regulation of the gene expression of bone morphogenetic protein(s) (BMPs) in said targeted tissue as measured by mRNA when said field is applied to the targeted tissue containing said BMPs, and exposing the targeted tissue to a field generated by the specific and selective field generated by said field generating device upon application of said at least one specific and selective signal thereto for a predetermined duration of time at a predetermined intervals duty cycle from approximately 10%-100% so as to selectively up-regulate the gene expression of BMPs in said targeted tissue as measured by mRNA. Claim 2 specifies within claim 1 that the generating step comprises the step of selectively varying the amplitude, duration, duty cycle, frequency, and waveform of the specific and selective signal until the up regulation of the gene expression of BMPs in said targeted tissue as a result of exposure to the resultant specific and selective field as measured by mRNA in ~ the targeted tissue by the generated field is substantially increased. Claim 3 specifies within claim 1 that said generating step comprises the step of generating the specific and selective signal at a remote source and said exposing step comprises the step of applying the field generated by the field generating device upon application of said specific and selective signal thereto specific and selective signal to the targeted tissue. Claim 4 specifies within claim 3 that the exposing step comprises the step of applying the specific and selective signal to at least one electrode, at least

one coil or a solenoid located near the targeted tissue. Claim 5 specifies within claim 4 that the exposing step comprises the step of applying the field generated by the field generating device upon application of said specific and selective signal thereto to the targeted tissue through one of capacitive coupling and inductive coupling. Claim 6 specifies within claim 5 that when the specific and selective signal is applied to said at least one electrode, said at least one electrode generates causes the electrodes to generate a capacitive coupling electric field, and when the specific and selective signal is applied to the at least one coil or solenoid, said at least one coil or solenoid generates to generate an electromagnetic field or a combined field. Claim 7 is drawn to a method for treating at least one of a bone fracture, fracture at risk, delayed union, nonunion, bone defect, spine fusion, osteonecrosis, and osteoporosis, comprising the steps of generating at least one specific and selective signal having a frequency of 30 kHz to 120 kHz that when applied to a field generating device operatively disposed with respect to targeted tissue causes the generation of a field having an amplitude of about 2 to 40 mV/cm in the targeted tissue that is specific and selective for the up-regulation of that up regulates the gene expression of bone morphogenetic protein(s) in said targeted tissue as measured by mRNA when said field is applied to the targeted tissue containing said BMPs; and exposing the targeted tissue to a field generated by the specific and selective field generated by said field generating device upon application of said at least one specific and selective signal thereto for a predetermined duration of time at a predetermined intervals duty cycle from approximately 10%-100% so as to selectively up-regulate gene expression of bone morphogenetic protein in said targeted tissue as measured by mRNA. Claim 8 specifies within claim 7 that the exposing step comprises the step of capacitively coupling or inductively coupling the specific and selective field to the targeted

tissue. Claim 9 specifies within claim 7 that the exposing step comprises the step of applying one of an electromagnetic field and a combined field to the targeted tissue. Claim 13 specifies within claim 7 that the generating step comprises the steps of selectively varying the amplitude, duration, duty cycle, frequency, and waveform of the specific and selective signal until the up-regulation of the gene expression of bone morphogenetic protein(s) as measured by mRNA in the targeted tissue by the resultant generated field is substantially increased. Claim 22 specifies a method of treating at least one of bone fractures, fractures at risk, delayed unions, nonunions, bone defects, spine fusion, osteonecrosis, and osteoporosis comprising the steps of exposing bone tissue to the specific and selective field generated by the device of claim 21 so as to up-regulate gene expression of bone morphogenetic protein(s) as measured by mRNA in the bone tissue. Claim 24 is drawn to a method of determining a specific and selective signal that when applied to a field generating device cause the field generating device to generate generates an electric field in targeted tissue that up-regulates bone morphogenetic protein(s) in the targeted tissue, comprising the steps of selecting a starting signal with a signal shape and frequency that when applied to said field generating device causes said field generating device to generate a field that is known to increase or suspected to affect cellular production of bone morphogenetic protein(s), selectively varying a duration of application of said starting signal until a duration that provides a most significant increase in production of BMP(s) is found, selectively varying an amplitude of said starting signal until an amplitude that provides a most significant increase in production of BMP(s) is found, selectively varying a duty cycle of the starting signal until a duty cycle that provides a most significant increase in production of BMP(s) is found, and selectively varying the duration of an on-off interval of the duty cycle of the signal until an on-off interval

that provides a most significant increase in production of BMP(s) is found. Claim 25 specifies within claim 24 the further steps of selectively varying a frequency and waveform of said starting signal and keeping other signal characteristics constant, until a greatest increase in the gene expression of BMP as measured by mRNA is found.

The instant claims recite bone morphogenetic proteins (BMPs) in the plural. However, application number 10/257,126, which matured into US Patent 7,465,566, only discloses BMP-2, and thus does not support the instant claims, which recite plural BMPs. As such, priority to 10/257,126 is not accorded, and an effective filing date of 11 January 2005 is granted for the instant claims.

Brighton et al. teaches, e.g., at the Abstract, methods and devices for the regulation of gene expression by cells via the application of specific and selective electric and electromagnetic signals so as to target diseased or injured tissue for treatment. At page 15, in the description of Figure 4, it is taught that aggrecan mRNA production in articular cartilage chondrocytes is stimulated by an electric field of 60 kHz at 20mV/cm, using capacitive coupling at various duty cycles. A duty cycle of 1 minute on/7 minutes off (12.5%) over 30 cycles produced a greater production of aggrecan mRNA than the control. At page 19, first full paragraph, it is taught that BMP-2 gene may be stimulated by the disclosed methods and devices.

The conditions taught by Brighton et al. for aggrecan and other genes overlaps considerably, i.e., many of the embodiments are the same, with the conditions recited in the instant claims for BMPs. These conditions thus would have been expected to have stimulated BMP expression along with aggrecan (or the other genes disclosed in Brighton et al. using such

overlapping conditions for expression). As such, these overlapping conditions would have anticipated the invention of the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
16 January 2009

/James S. Ketter/
Primary Examiner, Art Unit 1636